Summary of Safety and Effectiveness
Line Extension Opus Rod Fixation System

Submission Information

Name and Address of the Sponsor of the 510(k) Submission	Howmedica Osteonics Corp 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Karen Ariemma Regulatory Affairs Specialist
Date of Summary Preparation:	November 10, 2000

Device Identification

Proprietary Name:	Opus™ Rod Fixation System
Common Name:	Spinal Fixation Appliances
Classification Name and Reference:	Spinal Interlaminal Fixation Orthosis 21 CFR 888.3050 Pedicle Screw Spinal System 21 CFR 888.3070

Predicate Device Identification

The Opus™ Spinal System was determined substantially equivalent via 510(k) K993402. The Multi-Axial Cross-Connector (MAC) was determined substantially equivalent for use with the Osteonics® Spinal System via 510(k)s K990922 and K000965.

Device Description

The Opus™ Spinal System is made up of a range of screws, which are compatible with both the rod and plate components of the system. The components of the system are manufactured from ISO 5832/3 Titanium Alloy (Ti-6Al-4V). A complete component list is available in Appendix A.

The MAC is available in monoblock sizes of 17mm, 20mm, 23mm, and 26mm, and multi-axial sizes ranging from a 29mm-31mm span to a 66mm-131mm span. The MAC is manufactured from ISO 5832/3 Titanium Alloy (Ti-6Al-4V).

Intended Use:

The MAC is intended to be used with the other components of the Opus™ Spinal System.

K003490

Indications For Use:
The Opus™ Spinal System is intended for fixation of the T4-S2 spine. The specific indications for the Opus™ Spinal System are as follows:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the Opus™ Spinal System is indicated for one or more of the following: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

In addition, the Opus™ Spinal System is indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint, having fusions using autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (with pedicle placement at L3 and below) with removal of the implants after the development of a solid fusion mass.

Statement of Technological Comparison:
Fatigue testing demonstrates the comparable mechanical properties of the subject Opus™ Spinal System and MAC construct to the predicate constructs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 2000

Ms. Elizabeth A. Staub
Vice President, Quality Assurance/Regulatory Compliance/Clinical Research
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401

Re: K003490
Trade Name: Multi-Axial Cross-Connector (MAC) to the Opus™ Spinal System
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: November 10, 2000
Received: November 13, 2000

Dear Ms. Staub:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 003490

Device Name: Opus™ Spinal System

The Multi-Axis Cross-Connectors are intended to be used with the other components of the Opus™ Spinal System.

Indications For Use:

- When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the Opus™ Spinal System is indicated for one or more of the following: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

- In addition, the Opus™ Spinal System is indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint, having fusions using autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (with pedicle placement at L3 and below) with removal of the implants after the development of a solid fusion mass.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K003490